

Notice of Allowability

Application No.

09/896,811

Examiner

Amy A. Lewis

Applicant(s)

MADDEN ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the interview on 2 August 2005.
2. ☒ The allowed claim(s) is/are 1,30-33,35,36 and 38-40.
3. ☒ The drawings filed on 29 June 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 8/2/2005.
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

CHRISTOPHER S. F. LOW
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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Carol Laherty on 2 August 2005.

The application has been amended as follows:

See the attached Examiner's Amendments to the claims.

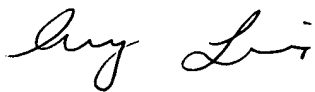
Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy A. Lewis whose telephone number is (571) 272-2765. The examiner can normally be reached on Monday-Friday, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy A. Lewis
Patent Examiner
Art Unit 1614



Christopher Low
SPE
Art Unit 1614

EXAMINER'S AMENDMENT TO THE CLAIMS

1. (Currently Amended) A liposomal topotecan unit dosage form, said unit dosage form comprising:

a lipid; and

a topotecan dosage of $0.01 \text{ mg/M}^2/\text{dose}$ to $7.5 \text{ mg/M}^2/\text{dose}$, wherein said liposomal topotecan unit dosage form has a drug:lipid ratio by weight of 0.05 to 0.2 and wherein said lipid comprises a mixture of sphingomyelin and cholesterol.

2. - 29. (Canceled)

30. (Currently Amended) A method of treating solid tumors in a mammal, said method comprising:

administering to said mammal having a solid tumor of the lung, mammary and/or colon a liposomal topotecan formulation comprising $0.01 \text{ mg/M}^2/\text{dose}$ to $7.5 \text{ mg/M}^2/\text{dose}$ of topotecan for an interval regime, wherein said liposomal topotecan formulation has a drug:lipid ratio by weight of 0.05 to 0.2 and wherein said liposome comprises a mixture of sphingomyelin and cholesterol for a time and under conditions effective to reduce and/or delay growth of the solid tumor mass.

31. (Previously Presented) The method of treating solid tumors of claim 30, wherein said interval regime is at least once a week.

32. (Previously Presented) The method of treating solid tumors of claim 30, wherein said interval regime is at least once every two weeks.

33. (Previously Presented) The method of treating solid tumors of claim 30, wherein said interval regime is at least once every three weeks.

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34. (Canceled)

35. (Previously Presented) The method of treating solid tumors of claim 30, wherein said interval regime is once a day for at least two consecutive days.

36. (Currently Amended) A liposomal camptothecin unit dosage form, said unit dosage form comprising a lipid, a camptothecin dosage of from 0.015 mg/M²/dose to 1 mg/M²/dose and having a drug:lipid ratio by weight of 0.05 to 0.2 and wherein said lipid comprises a mixture of sphingomyelin and cholesterol.

37. (Canceled)

38. (Previously Presented) The liposomal topotecan unit dosage form of claim 1, wherein said drug:lipid ratio by weight is 0.05 to 0.15.

39. (Previously Presented) The liposomal topotecan unit dosage form of claim 1, wherein said lipid comprises sphingomyelin and cholesterol in a molar ratio of 70:30 to 40:45.

40. (Previously Presented) The liposomal topotecan unit dosage form of claim 1, comprising from 1 mg/M²/dose to 4 mg/M²/dose of topotecan.

41. - 43.(Canceled)